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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

TOWA, RENE T

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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05/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/815,004

Applicant(s)

BECKMAN ET AL.

Examiner

Rene Towa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,8,9 and 11-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,8,9 and 11-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed March 19, 2007. Claims 1-2, 4-5, 8-9, and 11-24 are pending. Claims 3, 6-7 and 10 are cancelled. No new claims have been added. Claims 1, 4-5, 8-9, 12-13, 15 and 18-20 are amended.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 8-9, 11-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Fischer (US 5,286,257) further in view Burbank et al. (US Patent No. 6,662,041).

In regards to claim 1, Barsch disclose(s) a method of deployment of a biopsy marker at a biopsy surgical site within a body by use of a biopsy device, the method comprising:

- a probe 10 defining a cutter lumen 16 having proximal and distal openings, and
- a marker deployment rod 52 configured to be distally advanceable and proximally retractable through the cutter lumen 16;
- retracting the marker deployment rod 52 to expose the proximal opening of the cutter lumen 16;
- retracting a cutter 52 to expose a cutter lumen 16 of a biopsy probe 10;
- providing a biopsy marker introduction assembly comprising an introducer tube 44, a marker 42 disposed in the introducer tube 44, and a marker deployment rod 52

disposed for translation within the introducer tube 44, the marker deployment rod 52 having trailing and leading ends;

inserting the biopsy marker introduction assembly into the proximal opening of the cutter lumen 16; and

distally advancing the marker deployment rod 52 and thus the marker 42 to cause deployment at the biopsy surgical site (see fig. 4C, 5-6, & 11-12; column 1/lines 20-45; column 3/lines 7-28; column 5/lines 57-67; column 6/lines 35-51 & 58-66; column 7/lines 7-12, 17-28 & 36-42).

In regards to claim 8, Barsch disclose(s) a method, further comprising proximally extending the marker deployment rod 52 from the cutter lumen 16 wherein distally advancing the cutter 52 deploys the marker 42 as the cutter 52 approaches the cutter lumen 16 (see fig. 5; column 6/lines 58-66).

In regards to claims 9, Barsch disclose(s) a method, further comprising distally advancing the marker deployment rod 52 across a distal lateral opening 22 in the biopsy probe 10 enabling retraction of the biopsy probe 10 without disturbing the deployed marker 42 (see column 7/lines 7-12).

In regards to claim 11, Barsch disclose(s) a method, further comprising percutaneously deploying the marker 42 during a core needle biopsy procedure (see column 6/lines 35-51).

In regards to claim 12, Barsch disclose(s) a biopsy marker introduction device for deploying a biopsy marker 42 through a biopsy instrument having a probe 10 defining a cutter lumen 16 including a distal opening 22 and an accessible proximal opening and a

marker deployment rod 52 translatable through the cutter lumen 16, the device comprising:

- an introducer tube 44 configured to be received in the cutter lumen 16 and having a distal opening 48;

- a marker 42 slidably received in the tube 44; and

- a marker deployment rod 52 at least partially disposed in the introducer tube 44 proximal to the marker 42 and slidably received in the introducer tube 44, and the marker deployment rod 52 to deploy the marker 42 through the lateral distal opening 48 (see figs. 4C, 5-6, & 11-12; column 1/lines 20-45; column 3/lines 7-28; column 5/lines 57-67; column 6/lines 35-51 & 58-66; column 7/lines 7-12, 17-28 & 36-42).

In regards to claim 13, Barsch disclose(s) a device, further comprising a proximal collar 82 attached proximally to the introducer tube 44 and configured for manipulating the device into the cutter lumen 16 (see fig. 12).

In regards to claim 14, Barsch disclose(s) a device, further comprising an alignment feature (76, 78, 80) configured to rotationally orient the tube 44 in the cutter lumen 16 (see column 7/lines 36-42).

In regards to claim 15, Barsch disclose(s) a device, further comprising a pneumatic sealing feature (i.e. tight fit of plunger 52 to the wall of the tube 44) dynamically sealing the marker deployment rod 52 to the tube 44 (see column 5/line 67 to column 6/line 2).

In regards to claim 19, Barsch disclose(s) a device, wherein at least a portion of the tube 44 and marker deployment rod 52 comprise a resilient material for flexibly inserting the device into the biopsy instrument 10 (see figs. 4C & 5-6).

In regards to claims 1 and 12, Barsch discloses a system, as described above, teaches all the limitations of the claims except Barsch does not teach a plunger that is separable into a deployment rod and a cutter.

However, Fischer discloses an introduction device comprising a cutter 20 and a deployment rod 22; wherein the deployment rod 22 includes a cutter seat 68 proximate to the trailing end configured for abutment with a cutter 20; wherein the cutter seat 68 has a diameter greater than that of the cutter 20 (see figs. 2, 4-7; column 3/lines 1-6 & 24-68; column 4/lines 1-5).

Since Barsch discloses a plunger 52 (see fig. 4C & 6), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch with a plunger that is separable into a deployment rod and a cutter since such a modification would amount to a design choice, which serves the same purpose of moving the marker for deployment (see fig. 6). Moreover, Applicant has not disclosed that having a plunger that is separable into a deployment rod and a cutter provides an advantage, is used for a particular purpose, or solves a stated problem. Even further yet, it has previously been held that making separable is not patentable--See *In re Dulberg*, 289 F. 2d 522, 523, 129 USPQ 348, 349 (CCPA 1961).

Even moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch with a plunger that is separable into a deployment rod and a cutter similar to that of Fischer in order to deploy the marker by continued movement of the cutter.

Further in regard to claims 1 and 12, Barsch as modified by Fischer discloses a system, as described above, that teaches all the limitations of the claim including a deployment rod that distally terminates in a lateral opening with a ramped driving surface (see fig. 4C) except Barsch does not teach a distal opening including a ramped surface.

However, Burbank et al. ('041) disclose a device comprising lateral opening with a ramped driving surface (see fig. 6).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch as modified by Fischer with a lateral opening with a ramped driving surface similar to that of Burbank et al. in order to readily bias the marker out of the device.

3. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Burbank et al. ('041) in view of Fischer ('257) even further in view of Lamoureux et al. (US Patent No. 6,554,760).

Barsch as modified by Fischer and Burbank et al. discloses a device, as described above, that teaches all the limitations of the claim except Barsch as modified by Burbank et al. does not teach a removable sealing tip.

However, Lamoureux et al. disclose a device comprising a removable sealing tip 32 engageable over the deployment opening (see fig. 1).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Barsch as modified by Fischer and Burbank et al. with a seal similar to that of Lamoureux et al. in order to seal the biopsy needle and keep the marker from spilling out of the needle or body fluid from entering the needle prematurely (see Lamoureux et al., column 4/lines 22-24).

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Fischer ('257) further in view of Burbank et al. ('041) even further in view Burbank et al. (US Patent No. 6,161,034).

Barsch as modified by Fischer and Burbank et al. ('041) discloses method as described above and further as follows:

In regards to claim 2, a method wherein a distal portion of the cutter lumen 16 communicates with a pneumatic source (see Barsch, column 1/lines 20-45).

In regards to claims 6, Barsch as modified by Fischer and Burbank et al. ('041) ('041) disclose(s) a method, further comprising sizing a thickness of the introducer tube 44 to enable advancing the cutter 52 into the cutter lumen 16 with the introduction assembly inserted therein, wherein distally advancing the cutter 52 comprises distally advancing the cutter 52 into the cutter lumen 16 (see Barsch, see fig. 4C & 5-6; column 6/lines 35-51 & 58-66).

Barsch as modified by Fischer and Burbank et al. ('041) discloses a method, as described above, that teaches all the limitations of the claim including except Barsch as

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modified by Fischer and Burbank et al. ('041) does not teach the step of insufflating the biopsy surgical site with the pneumatic source.

However, Burbank et al. disclose a method comprising the step of insufflating the biopsy surgical site (see Burbank et al. ('034), see column 14/lines 10-17 & 24-26).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Barsch as modified by Fischer and Burbank et al. ('041) with a method step similar to that of Burbank et al. in order to accommodate fluid filled markers that are detectable by ultrasound or X-ray (see Burbank et al. ('034), see column 14/lines 24-26).

5. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Fischer ('257) further in view of Burbank et al. ('041) even further in view Zarins et al. (US Patent No. 6,605,047).

Barsch as modified by Fischer and Burbank et al. ('041) discloses a method, as described above, that teaches all the limitations of the claim except Barsch as modified by Fischer and Burbank et al. ('041) does not teach the step of forming a pneumatic seal between the deployment rod and the introducer tube.

However, Zarins et al. discloses a method comprising the step of forming a pneumatic seal 78 between the deployment rod 30 and the introducer tube 58 wherein distally advancing the cutter 30 forms a syringe pressure proximally to the pneumatic seal 78 (see fig. 3I; column 9/line 65 to column 10/line 13; column 10/lines 18-21).

It would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a method similar to that of Barsch as modified by Fischer

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and Burbank et al. ('041) with a method step similar to that of Zarins et al. in order to deploy the marker out of the marker seat (see column 10/lines 9-13).

Moreover, since Zarins et al. further discloses replacing the plunger altogether with a fluid actuation system (i.e. a syringe) (see column 10/lines 22-25), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Barsch as modified by Fischer, Burbank et al. ('041) and Zarins et al. with a pressure-drawn deployment rod (i.e. plunger of a syringe) since such a modification would amount to a design choice.

6. Claims 20-21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Fischer ('257) further in view of Burbank et al. ('041) even further in view of Miller et al. (US Patent No. 6,638,235).

In regards to claim 20, Basch discloses a marker introduction device comprising:
a tube 44 configured to be received in the cutter lumen 16 and having a lateral distal opening,

a marker 42 slidably received in the tube, and

a marker deployment rod 52 proximal to the marker 42 and slidably received in the tube 44, and having a proximal extension 70 configured for abutment with the cutter 52 to deploy the marker 42 through the lateral distal opening (see figs. 4C, 5-6, & 11-12; column 1/lines 20-45; column 3/lines 7-28; column 5/lines 57-67; column 6/lines 35-51 & 58-66; column 7/lines 7-12, 17-28 & 36-42).

In regards to claim 21, Barsch disclose(s) a marker introduction device, wherein the marker deployment rod 52 is operably configured to dynamically seal to the tube 44 (see column 5/line 67 to column 6/line 2).

In regards to claim 24, Barsch disclose(s) a marker introduction device, wherein the marker deployment rod 52 is operably configured to close the distal opening 22 in the biopsy probe 10 subsequent to marker deployment (see column 7/lines 2-5).

Barsch discloses a system, as described above, teaches all the limitations of the claims except Barsch does not teach a plunger that is separable into a deployment rod and a cutter.

However, Fischer discloses an introduction device comprising a cutter 20 and a deployment rod 22; wherein the deployment rod 22 includes a cutter seat 68 proximate to the trailing end configured for abutment with a cutter 20; wherein the cutter seat 68 has a diameter greater than that of the cutter 20 (see figs. 2, 4-7; column 3/lines 1-6 & 24-68; column 4/lines 1-5).

Since Barsch discloses a plunger 52 (see fig. 4C & 6), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch with a plunger that is separable into a deployment rod and a cutter since such a modification would amount to a design choice, which serves the same purpose of moving the marker for deployment (see fig. 6). Moreover, Applicant has not disclosed that having a plunger that is separable into a deployment rod and a cutter provides an advantage, is used for a particular purpose, or solves a stated problem. Even further yet, it has previously been held that making

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separable is not patentable--See *In re Dulberg*, 289 F. 2d 522, 523, 129 USPQ 348, 349 (CCPA 1961).

Even moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch with a plunger that is separable into a deployment rod and a cutter similar to that of Fischer in order to deploy the marker by continued movement of the cutter.

Barsch as modified by Fischer discloses a system, as described above, that teaches all the limitations of the claim including a deployment rod that distally terminates in a lateral opening with a ramped driving surface (see fig. 4C) except Barsch does not teach a distal opening including a ramped surface.

However, Burbank et al. ('041) disclose a device comprising lateral opening with a ramped driving surface (see fig. 6).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch as modified by Fischer with a lateral opening with a ramped driving surface similar to that of Burbank et al. in order to readily bias the marker out of the device.

Moreover, Barsch discloses a system, as described above, that teaches all the limitations of the claim including a deployment rod that distally terminates in a lateral opening with a ramped driving surface (see fig. 4C) except Barsch does not teach a distal opening including a ramped surface. However, Burbank et al. ('041) disclose a device comprising lateral opening with a ramped driving surface (see fig. 6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was

made to provide a system similar to that of Barsch with lateral opening with a ramped driving surface similar to that of Burbank et al. in order to readily bias the marker out of the device.

Although Basch as modified by Fisher and Burbank ('041) teaches the use of a biopsy system (see fig. 4B), Basch as modified by Fisher and Burbank ('041) does not explicitly disclose the features of the biopsy probe.

However, Miller et al. discloses a biopsy probe as follows:

In regards to claim 20, Miller et al. disclose(s) a core biopsy probe 10 including a cutter lumen (27, 34) that communicates between a distal opening 25 and an accessible proximal opening 100;

a biopsy handle 12 having an actuator 22 for cutting the biopsy sample through the biopsy probe 10 (see figs. 1-2; column 7/lines 4-6 & 21-23; column 8/lines 49-50 & 61-64; column 45-48).

Even moreover yet, It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Basch as modified by Fisher and Burbank ('041) with a biopsy probe similar to that of Miller et al. in order to mark the biopsy site without retracting the biopsy probe and thus maintaining the percutaneous site (i.e. similar in function to an introducer sheath) (see Barsch, fig. 4B).

7. Claims 22-23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Fischer ('257) further in view of Burbank et al. ('041) even further in view of Miller et al. et al. ('235) even further yet in view of Zarins et al. ('047).

Barsch as modified by Fisher, Burbank et al. ('041) and Miller et al. et al. discloses a system, as described above, that teaches all the limitations of the claim except Barsch as modified by Fisher, Burbank et al. ('041) and Miller et al. et al. does not system with a pressure-drawn deployment rod that is capable of insufflating a surgical site.

However, Zarins et al. discloses a system comprising a pneumatic seal 78 between the deployment rod 30 and the introducer tube 58 wherein distally advancing the cutter 30 forms a syringe pressure proximally to the pneumatic seal 78 (see fig. 31; column 9/line 65 to column 10/line 13; column 10/lines 18-21).

It would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a system similar to that of Barsch as modified by Fisher, Burbank et al. ('041) and Miller et al. et al. as further modified by Miller et al. with an actuation system similar to that of Zarins et al. in order to deploy the marker out of the marker seat (see column 10/lines 9-13).

Moreover, since Zarins et al. further discloses replacing the plunger altogether with a fluid actuation system (i.e. a syringe) (see column 10/lines 22-25), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch as modified by Fisher, Burbank et al. ('041) and Miller et al. et al. as further modified by Zarins et al. with a pressure-drawn deployment rod (i.e. similar to a vacuum-actuated syringe plunger) that is capable of insufflating the surgical site since such a modification would amount to a design choice.

Response to Arguments

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8. Applicant's arguments filed March 19, 2007 have been considered but are moot since they do not address any the rejections submitted on the last Office action dated October 20, 2006.

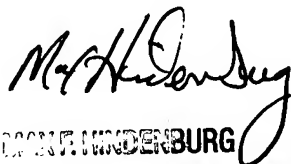
Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT


MAX HINDENBURG
ELECTRONIC PATENT EXAMINER
ELECTRONIC BUSINESS CENTER 3700